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<b>(54) Title:</b> IMPLANTABLE VASCULAR ACCESS DEVICE  <b>(57) Abstract</b>  <p>The present invention provides an improved vascular access port (10) comprising a port base (10) with a metallic dish insert (14) molded (or bonded) into the bottom of the reservoir (22). In one embodiment, single reservoir (22) is provided (fig. 2). In another embodiment, plural reservoirs (22a, 22b) are provided (fig. 1). The metallic bottom (14) of the reservoir provides a hard surface that will resist abrasion and puncture by the access needles used to infuse medication or withdraw blood. Additionally, the single and dual ports can include exit ports (18) that are intended to better anatomically fit into the subcutaneous areas around the muscle tissue.</p> <div data-bbox="998 1150 1437 1501" data-label="Image"> </div>		

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# IMPLANTABLE VASCULAR ACCESS DEVICE

## BACKGROUND OF THE INVENTION

### 1. Field of the Invention

The present invention relates generally to a subcutaneously implantable vascular access port. More specifically, the present invention relates to an access port having a single needle-penetrable, self-sealing septum which affords repeated access to a plurality of distinct fluid cavities having staggered outlet ducts in communication with a plural lumen catheter.

### 2. Description of Related Art

Access portals, or ports, provide a convenient method to repeatedly deliver medicants to remote areas of the body without utilizing surgical procedures. The port is totally implantable within the body, and permits the infusion of medications, parenteral solutions, blood products, and other fluids. The port may also be used for blood sampling.

Known ports typically include a chamber accessible through a self-sealing septum. Septums of the prior art vary in shape, from a wafer-like cylindrical block of silicone to a pre-molded septum of U.S. Pat. No. 4,802,885 to Weeks et al. The pre-molded septum of U.S. Pat. No. 4,802,885 includes opposed convex surfaces and a peripheral ledge.

In common practice, a caregiver locates the septum of the port by palpitation. Port access is accomplished by percutaneously inserting a needle, typically a non-coring needle, perpendicularly through the septum of the port and into the chamber. The drug or

1 fluid is then administered by bolus injection or continuous infusion. Ordinarily the fluid  
2 flows through the chamber, into a catheter and finally to the site where the fluid is  
3 desired. Except for the septum, traditional ports are constructed from all-metal or all-  
4 plastic. Each type of construction has unique advantages and disadvantages.

5 All-metal constructions have the advantages that they maintain a septum in a self-  
6 sealing fashion after repeated percutaneous injections. Additionally, all-metal  
7 constructions, such as titanium, or stainless steel provide a port which is both  
8 biocompatible and compatible with the injected fluid.

9 However, all-metal constructions present the disadvantages that they are  
10 relatively heavy, difficult to fabricate and relatively expensive. Additionally, all-metal  
11 ports produce large Magnetic Resonance Imaging (MRI) artifacts. On the other hand,  
12 all-plastic ports have the advantages that they are inexpensive to construct, light in  
13 weight, and do not create an MRI artifact. However, ports constructed from plastic have  
14 the disadvantage that infused fluids may react with the plastic body of the port. All-  
15 plastic ports contain the disadvantage that they cannot maintain a sealing engagement  
16 with the septum after repeated percutaneous injections. Additionally, all-plastic ports are  
17 susceptible to nicks and scratches on the interior surface by the accessing needle. These  
18 nicks and scratches could lead to nidus, blood clots, or precipitation formations.

19 Efforts have been made to combine the advantages of all-metal ports with all-  
20 plastic ports. For example, in U.S. Pat. No. 4,802,885 to Weeks et al., a metal reservoir  
21 having a chamber sealed by a pre-formed silicone septum is jacketed by a single piece of  
22 a silicone elastomer. However, all-metal ports jacketed by a single piece of elastomer

1 have significant shortcomings. These shortcomings include quality control problems  
2 during manufacturing, and expensive molding processes.

3 Other efforts have focused on providing a multiple piece all-plastic housing in  
4 cooperation with an open metal cup to sealingly engage a septum. For example, see U.S.  
5 Pat. No. 5,213,574 to Tucker. This design has shortcomings associated with it, including  
6 defects in the plastic housing which may cause an improperly sealed septum. Once the  
7 septum is improperly sealed the entire port must be discarded.

8 Therefore a need has arisen for an access port device which addresses the  
9 problems of prior port devices.

10 A variety of implantable devices, known as subcutaneous access ports, are  
11 utilized to deliver fluids to or to withdraw fluids from the bloodstream of a patient. Such  
12 access ports typically include a needle-impenetrable housing which encloses one or more  
13 fluid cavities and defines for each such fluid cavity an access aperture communicating  
14 through the housing on the side thereof which is adjacent to the skin of the patient when  
15 the access port is implanted in the body. A needle-penetrable septum is received in and  
16 seals each access aperture. Exit passageways located in an outlet stem communicate with  
17 each of the fluid cavities for dispensing medication therefrom to a predetermined location  
18 in the body of the patient through an implanted catheter attached to the access port.

19 Once the access port and the catheter have been implanted beneath the skin of a  
20 patient, quantities of medication or blood may be dispensed from one such fluid cavity by  
21 means of a non-coring needle passed through the skin of the patient and penetrating the  
22 septum into one of the respective fluid cavities. This medication is directed through the

1 distal end of the catheter to an entry point into the venous system of the body of the  
2 patient.

3 Blood may also be withdrawn for sampling from the body of a patient through  
4 such an access port. This is accomplished by piercing the skin of the patient and one of  
5 the respective septums with a non-coring needle and applying negative pressure thereto.  
6 This causes blood to be drawn through the catheter into the fluid cavity corresponding to  
7 the pierced septum and then out of the body of the patient through the needle.

8 To prevent clotting thereafter, the withdrawal route is flushed with a saline  
9 solution or heparin using again a non-coring needle piercing the skin of the patient and  
10 the septum in the same manner as if a medication were being infused.

11 Both intermittent and continual injections of medication may be dispensed by the  
12 access port. Continual access involves the use of a non-coring needle attached to an  
13 ambulatory-type pump or a gravity feed IV bag suspended above the patient. The  
14 ambulatory-type pump or the IV bag continually feeds the medication or fluid through  
15 the needle to the fluid cavity in the access port and from there through the catheter to the  
16 entry point into the venous system.

17 To facilitate locating each respective septum once the access port has been  
18 implanted, some access ports incorporate a raised circular ring located about the outer  
19 perimeter of the septum. This raised ring enhances the tactile sensation afforded by the  
20 subcutaneous septum to the palpating fingertip of a medical practitioner. Alternatively,  
21 other access ports have utilized palpation ridges rather than a raised circular ring for

1 substantially the same purpose. The palpation ridges allow the location of the septum to  
2 be accurately determined when the access port is subcutaneously implanted.

3 To preclude reaction with the tissues in the body of the patient, access ports are  
4 constructed of nonreactive materials, such as titanium or stainless steel. Although these  
5 materials are nonreactive, access ports constructed utilizing titanium or stainless steel  
6 materials produce an interfering or blurred image of the body of the patient in the vicinity  
7 of the implanted access port when diagnostic imaging techniques such as magnetic  
8 resonance imaging ("MRI"), CAT scans, or computerized tomography are used. The  
9 blurred region caused by the presence of a metallic access port in the body of a patient  
10 extends beyond the access port itself. Therefore, the use of metallic access ports limits  
11 the diagnostic imaging techniques that may be used relative to those areas of the body in  
12 which an access port is implanted. In place of metallic materials some access ports have  
13 been fabricated at least in part from biocompatible plastics.

14 A further problem relating to the materials for and manufacture of access ports is  
15 the deleterious impact of some manufacturing procedures on the fluids which flow  
16 through the fluid cavities and related structures located between the fluid cavities and the  
17 catheter. During the manufacture of an access port, whether the port is comprised of  
18 metallic or plastic materials, it becomes necessary to form the fluid cavities and exit  
19 passageways through which the fluid will be directed into the attached catheter. This  
20 manufacturing process often leaves sharp edges, seams and corners in the areas where the  
21 fluid cavity is to direct the flow of the fluid through an exit passageway. As blood or  
22 other fluids are injected through the septum into the fluid cavity, pressure developed

1 within the fluid cavity tends to cause fluid to flow through the exit passageway. As the  
2 fluid in the fluid cavity flows past the sharp edges and corners produced in the  
3 manufacture of the access port, turbulence arises, taking the form of a vortex, adjacent to  
4 the sharp edges and corners. Some fluids, such as blood, are sensitive to this turbulence,  
5 and lysing of the red blood cell component of the injected blood can occur in these  
6 turbulent areas.

7 In addition, the production of the circular fluid cavities often results in the  
8 creation of areas within the housing in which fluid flow is retarded. These areas are  
9 referred to as dead spaces and usually occur in areas of transition, such as where the  
10 bottom of the septum interfaces with the walls of the fluid cavity and where the floor of  
11 the fluid cavity meets the exit passageway through which the fluid must flow. As the  
12 flow of fluids through dead spaces is retarded, stagnation occurs, resulting in some fluid  
13 being trapped within these dead spaces. If the access port is used to withdraw or  
14 transfuse blood, blood trapped in these dead spaces may form clots and block the flow of  
15 fluid through the fluid cavity.

16 Moreover, in some prior vascular access ports the internal reservoirs are formed  
17 by two plastic parts which are bonded together. This results in an undesirable seam being  
18 formed where the adjacent parts abut one another. The inside of the reservoir should be  
19 as smooth as possible to help prevent damage to blood cells or the initiation of blood  
20 clotting during infusion or withdrawal of blood through the port.

21 A further problem encountered in the design and construction of access port  
22 relates to the positioning of the septums within the housing of the access port. The

1 positioning of the septums within the housing is a compromise between two conflicting  
2 objectives. These are the need to separate the septums to such a distance so that the  
3 septums may be easily differentiated for the purpose of injection and the need to restrict  
4 the overall dimensions of the access port for patient comfort and aesthetics. The  
5 distancing of the septums to facilitate their differentiation, however, results in a  
6 corresponding distancing of the fluid cavities. This result is at odds with another  
7 structural requirement for access ports with plural cavities, namely that the exit  
8 passageways from each fluid cavity be closely spaced at the point where the implanted  
9 catheter is to be coupled to the access port.

10 To guide the flow of a fluid from each of the spatially separated fluid cavities into  
11 the side-by-side configuration of fluid outflow necessitated by the dimensions of a plural  
12 lumen catheter, intermediate structural members have been required. Naturally, this  
13 complicates the process of manufacture and increases its cost, as well as the chances of  
14 structural failure.

15 There are several examples of such intermediate members used to resolve the  
16 manufacturing constraints imposed upon the construction of a passageway flowing from  
17 spatially separate fluid cavities into a side-by-side configuration acceptable by a catheter.  
18 One is to produce passageways in the form of bent metal tubes which are then insert  
19 molded or welded into the larger body of the access port. The use of such a metal  
20 component will interfere with the production of an access port which is free of limits as  
21 to the diagnostic imaging techniques that may be used relative to those areas of the body  
22 in which an access port is implanted. In addition, the integral nature of such metal outlet

1   passageways raises the possibility of leakage of medication through the interstices  
2   between the metal tubes and the body of the access port.

3           Alternatively, to produce fluid flow from spatially separated fluid cavities into the  
4   closely spaced lumens of a catheter, each fluid cavity has been designated with its own  
5   spatially separated outlet stem. These outlet stems are then coupled by a hub structure  
6   for permanent attachment to the closely spaced lumens of a catheter. This type of  
7   arrangement increases the size of the overall access port and its cost of manufacture by  
8   adding thereto the necessity of fabricating and assembling of the hub element. Port  
9   connections to catheters in this manner are permanent. Accordingly, if the catheter is to  
10   be shortened by trimming, that trimming must occur at the distal end of the catheter, and  
11   this precludes the use of any type of specially designed tip or valve.

12           An additional set of problems encountered in the use of access ports relates to the  
13   actual connection of the catheter to the access port. This is most commonly effected by  
14   securing the catheter to an outlet stem protruding from the housing of the access port. In  
15   an attempt to lock the catheter to the outlet stem of the access port, thread-type systems  
16   have been developed wherein the catheter is attached to an outlet stem, and the outlet  
17   stem is then threaded into the access port. When utilizing this system, however, it is  
18   difficult to determine the amount of engagement of the catheter onto the outlet stem.  
19   Some catheter connection systems do not allow visual verification of attachment. As a  
20   result, leakage and failure can occur.

21           To overcome this problem, access ports are produced in which the catheter is pre-  
22   attached at the factory. While this practice alleviates many of the problems with leakage

1 and failure due to catheter slippage, this system severely limits the type of the catheter  
2 usable with the access port. This precludes the use of catheters having specialized distal  
3 tips, as the distal end of the catheter is the only end that can then be trimmed to effect its  
4 ultimate sizing. For example, catheters utilizing a Groshong.RTM. slit valve at their  
5 distal end may not have any of the distal tip of the catheter removed without  
6 compromising the catheter.

7 Thus, there has been a need for an improved vascular access port which  
8 overcomes the above-noted problems, and which can be manufactured economically.  
9 The present invention fulfills these needs and provides other related advantages.

#### 10 SUMMARY OF THE INVENTION

11 Accordingly, the present invention provides an improved vascular access port  
12 comprising a plastic port base with a metallic dish insert molded (or bonded) into the  
13 bottom of the reservoir. In one embodiment, a single reservoir is provided. In another  
14 embodiment, plural reservoirs are provided. The metallic bottom of the reservoir  
15 provides a hard surface that will resist abrasion and puncture by the access needles used  
16 to infuse medication or withdraw blood. The features of both the single and dual ports  
17 include 'duck tail' rears. This feature is intended to better anatomically fit into the  
18 subcutaneous areas around muscle tissue. The plastic must be of a bio-compatible and  
19 chemically-compatible material such as Nylon, Poly Acetals, or Polyethersulphone. The  
20 chemical resistance is necessary so that the injected medications do not react with the  
21 port materials. The yield and creep strength and flexure modulus of the material is  
22 important so that the plastic will hold and retain the port top retaining the septum.

1           In the preferred embodiment, the present invention provides an implantable  
2   access port, comprising a housing member defining at least one fluid chamber. A cup  
3   member is attached to the housing member and defining the bottom of the fluid chamber.  
4   A permeable septum member is attached to the housing and defining the top of the fluid  
5   chamber and having a tactile or visual location marker portion on the outer surface  
6   thereof. An exit port is provided to permit egress of fluid from within the fluid chamber.

7           The cup may be made of stainless steel, titanium or ceramic (alumina or  
8   zirconium). All these materials are biologically and chemically inert so that they will not  
9   react with the body or medications. The insert is formed, cast, machined or molded into a  
10   'dish' shape with the edges being of a radius greater than .035". This radius is important  
11   for the reduction of coagulation and turbulence of the blood and medication within the  
12   reservoir.

13          The port assembly can include a top or retaining ring(s). This top retains the  
14   rubber septum. It can be made of the same plastic material as the base; in which case, it  
15   can be fit, bonded or ultra-sonically welded to the base after septum placement. It can be  
16   a metallic material as mentioned above for the dish insert. For these applications the  
17   attachment of the top can be achieved by interference fits, bonding with a biocompatible  
18   epoxy or by various welding means (ultrasonic, friction, or thermal melt).

19          Each port has a stem or catheter adapter which enables a fluid path between the  
20   reservoir and the external catheter traveling to the vascular area. Stems are made from  
21   biocompatible and chemically inert materials that are also strong such as stainless steel or  
22   titanium. The stem for the single port has one fluid channel straight through its body. The

1 dual version has two channels which angle out to the sides in order to meet with the walls  
2 of the reservoirs. Both these stems have barbs for locking into the plastic body. Barb(s)  
3 are also found on the distal end for attachment to the catheter. The dual version has a  
4 split between the channel holes in order to allow a bi-lumen catheter to attach.

5 The septums for these ports are intended to assist in the location (and in the case  
6 of the dual port) differentiation of the reservoir location. The combinations for these may  
7 vary for application preferences. The two styles include concave and convex shapes.  
8 After the surgical implantation, the local is determined by palpitation of the skin over the  
9 port. For the illustration shown, the concave side feels different than the convex side. The  
10 convex feature has a nipple shape. Both septums are designed to fit into the port body  
11 and be retained by the port top. The septum is intended to be self sealing under the  
12 pressures produced by the vascular system and the injection pressures of injections. This  
13 is achieved by controlling the rubber hardness and the dimensions relative to the retained  
14 assembly. The interference fit or squeezing of the septum rubber creates a residual  
15 pressure radially toward the center of the septum. The softness of the rubber allows the  
16 punctures to reseal without leakage. It is preferred that non-coring needles are used by  
17 clinical staff to avoid excessive reduction of material and coring or skiving material into  
18 the reservoir which flow into the blood stream. The rubber material commonly used for  
19 septums is silicone, but other biocompatible elastomer materials may be used.

20 Advantageously, the present invention provides low cost, yet durable  
21 subcutaneous vascular access port(s). The port(s) can be manufactured from  
22 biocompatible grades of plastics and metals which meets the safety and clinical parameters

1 of implanted devices. This plastic port features a metallic (titanium, stainless steel or  
2 ceramic) dish which will be insert molded pressed, or bonded into the base of the port  
3 reservoir to prevent potential penetration of needles through the base of a typical style  
4 plastic port. Also advantageously, the port of the present invention features a titanium  
5 shield molded into a plastic port top around the rubber septum to prevent needle  
6 mislocation, false needle locations and potential medication misdirection. The port  
7 septums have incorporate in them indication features to distinguish which port reservoir  
8 the surgeon or nurse is accessing and better locates the reservoir center. These features  
9 are utilized in other dual lumen ports by an indication on the port itself, but not on the  
10 septum.

11 Other features and advantages of the present invention will become apparent as  
12 the following Detailed Description proceeds, and upon reference to the Drawings,  
13 wherein like numerals depict like parts, and wherein:

14 BRIEF DESCRIPTION OF THE DRAWINGS

15 Figures 1A-1D depict various views of the preferred dual-port implantable access  
16 device of the present invention;

17 Figures 2A-2E depict various views of the preferred single-port implantable  
18 access device of the present invention;

19 Figure 3A-3D depict various views of another embodiment of the implantable  
20 access device of the present invention;

21 Figure 4 depicts an alternative embodiment of the cup member of Figures 1-3;  
22 and

1           Figures 5A and 5B depict views of another alternative embodiment of the cup  
2 member of Figures 1-3.

3           Detailed Description of Preferred Embodiments

4           Figures 1A-1D depict various views of the preferred dual-port implantable access  
5 device 10 of the present invention. The port 10 generally comprises a housing member  
6 12 defining fluid chambers 22A and 22B. The chambers are sealed by the housing 12,  
7 bottom cup members 14A and 14B, and self-sealing septum members 16A and 16B. In  
8 this embodiment, the housing 12 is preferably formed of titanium, stainless steel,  
9 ceramic, and/or other biocompatible material. The septum 16A and 16B is preferably  
10 formed of silicon or other semi-permeable materials that permit ingress and egress of  
11 needles to deliver fluid to the chambers 22A and/or 22B. An exit port 18 is provided in  
12 communication with chambers 22A and 22B, which delivers fluid out of the chambers  
13 22A and/or 22B to a predetermined location, via stem 20 and attached catheter (not  
14 shown), as is understood in the art.

15           The septums 16 are formed with a generally circular shape, and, as shown in the  
16 drawings, may include a nipple 26 or a concave portion 28 on the outer surface thereof.  
17 The nipple is advantageous for visual and/or tactile location of the port device 10, and as  
18 a locator for needle insertion. Likewise, concave portion 28 provides similar features,  
19 but may be used in areas where a protruding nipple is undesirable. The septums 16A and  
20 16B and housing 12 are preferably formed with mated tongue and groove portions, as  
21 shown in the side view drawings of Figures 1A and 1C. The housing may further include  
22 molded top member 24 which press against the septum for further stability.

1           As opposed to plastic materials used in the prior art, the cup portion 14 is  
2     preferably formed of titanium or stainless steel to resist scratches and/or debris from  
3     being introduced into the chambers, as a result of needle impacts thereon. Preferably,  
4     cup 14A and 14B is attached to housing 12 via insert molding, interference fit, ultrasonic  
5     weld, biocompatible glue, and/or other attachment means. Figures 2A-2E depict a  
6     single-port version of the port device of the present invention, and is similarly  
7     constructed as shown in Figure 1A-1D.

8           Figure 3A-3D depict another embodiment of the port device of the present  
9     invention. In this embodiment, the cup member 14' includes sidewall portions 28 that  
10    are dimensioned to fit within the chamber 22', defined by housing 12'. The cup member  
11    14' is attached to the housing 12' by insert molding, interference fit, ultrasonic weld,  
12    biocompatible glue, or other attachment means known in the art. The septum 16' is  
13    similar to the septum 16A and/or 16B and may also include a nipple or concave portion,  
14    described above. In this embodiment, a metal ring 30 is provided which circumscribes  
15    the top of the housing 12' and is positioned above the septum 16'. The ring 30 preferably  
16    includes flange members 32, which have an upper surface dimensioned so as to urge a  
17    needle downward toward the septum, thus preventing errant entry of needles within the  
18    septum. In this embodiment the ring structure is formed of titanium, stainless steel or  
19    ceramic material for increase mechanical resistance to puncture and/or tear.  
20    Accordingly, since the ring member 30 will protect the other components, the housing  
21    can be formed of less expensive material, e.g., plastics, etc. The ring member 30 and  
22    housing 12' preferably include mated tongue and groove portions to hold the ring

1 member securely against the housing, as shown. Additionally, the lower surface of the  
2 flange members 32 are dimensioned so as to force against the septum, thereby holding  
3 the septum in place.

4       Figures 4 and 5A-5B depict alternative embodiments for the cup member  
5 described above in Figures 1-3. In the embodiment of Figure 4, the cup member 14''  
6 defines an exit port 18' therein, and preferably located at the bottom portion of the cup  
7 14'', as shown. A stem 20' is connected to the port 18' at one end, and a catheter 36 is  
8 connected to the other end of the stem 20'. So as to provide a low-profile shape, it is  
9 preferred that the stem 20' includes an elbow, or angled portion, to direct fluid sideways  
10 away from the port, as shown. In Figures 5A and 5B, the cup 14''' is formed with a  
11 flange 40 to define an opening 38 that is dimensioned to accept a stem 20'' therein. The  
12 cup 14'' and/or 14''' are provided to better anatomically fit into the subcutaneous areas  
13 around muscle tissue, and each are connected to the housing (not shown) in a manner  
14 similar to the embodiments of Figures 1, 2 or 3.

15       Thus, it is apparent that there has been provided an implantable vascular access  
16 device that satisfies the objectives set forth herein. Those skilled in the art will recognize  
17 that the present invention is subject to modification and/or alterations, all of which are  
18 deemed within the scope of the present invention, as defined in the appending claims.

CLAIMS

- 1  
2 1. An implantable access port, comprising a housing member defining at least one  
3 fluid chamber, a cup member attached to said housing member and defining the bottom  
4 of said fluid chamber, a permeable septum member attached to said housing and defining  
5 the top of said fluid chamber and having a tactile or visual location marker portion on the  
6 outer surface thereof, and an exit port to permit egress of fluid from within said fluid  
7 chamber.
- 8 2. An access port as claimed in claim 1, further comprising a stem member in fluid  
9 communication with said exit port.
- 10 3. An access port as claimed in claim 1, wherein said cup member being formed of a  
11 material selected from titanium, stainless steel and ceramic.
- 12 4. An access port as claimed in claim 1, wherein said septum being formed of  
13 silicon, and permitting the ingress and egress of needles to deliver fluid to said fluid  
14 chamber.
- 15 5. An access port as claimed in claim 1, wherein said housing being dimensioned so  
16 as to be placed within a predetermined position under skin.
- 17 6. An access port as claimed in claim 1, wherein said housing being formed of a  
18 material selected from titanium, stainless steel and ceramic.
- 19 7. An access port as claimed in claim 1, wherein said cup member including a flange  
20 member on the bottom portion thereof defining an opening, said opening defining said  
21 exit port.

- 1    8.      An access port as claimed in claim 1, further comprising a ring member located  
2    on the top portion of said housing member and surrounding said septum, said ring  
3    member including flange portions dimensioned to urge a needle toward said septum and  
4    to hold said septum against said housing.
- 5    9.      An access port as claimed in claim 1, wherein said tactile or visual location  
6    marker portion of said septum comprising a nipple on the outer surface thereof.
- 7    10.     An access port as claimed in claim 1, wherein said tactile or visual location  
8    marker portion of said septum comprising a concave portion on the outer surface thereof.

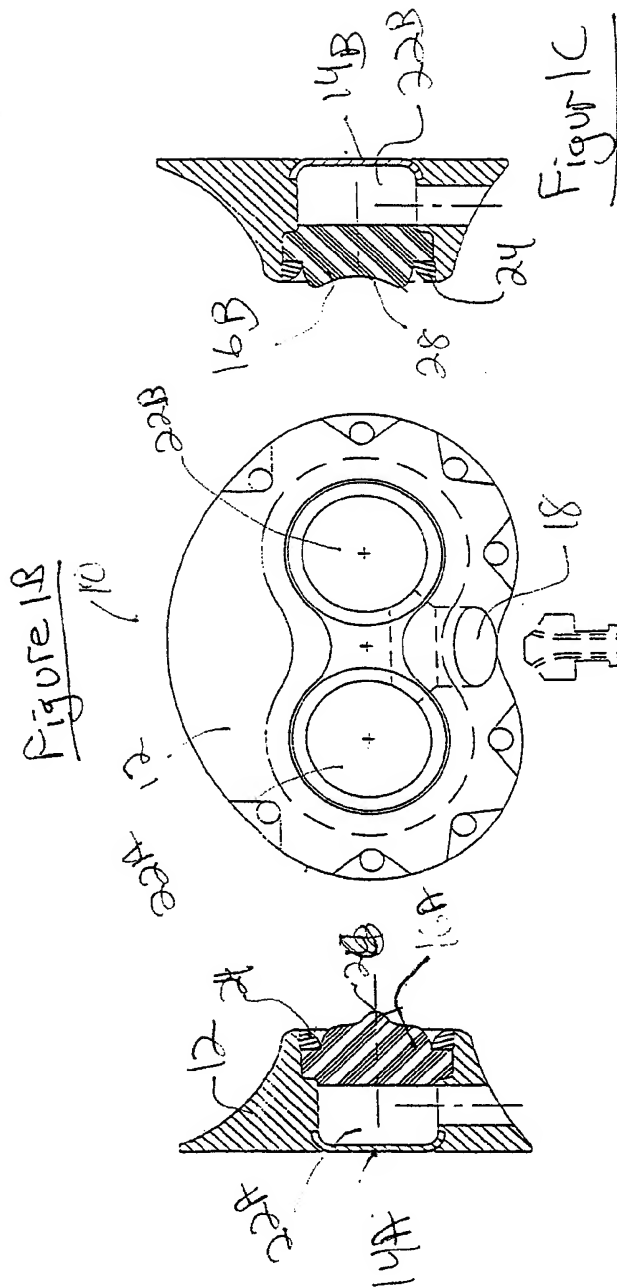


Figure 1A

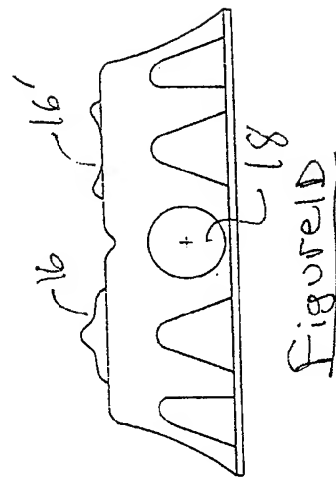


Figure 1

Figure 1B

Figure 2B  
10

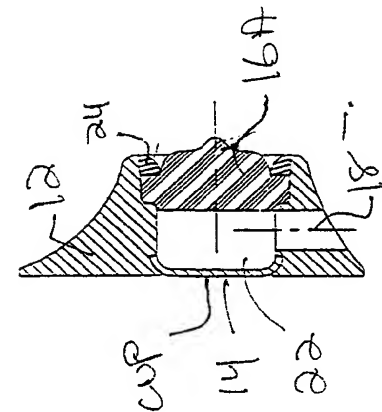
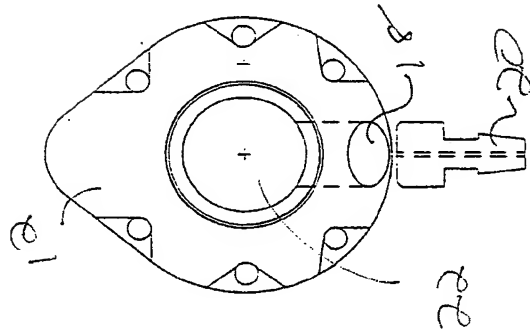


Figure 2A

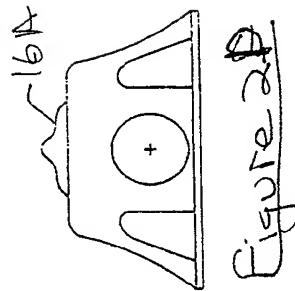


Figure 2D

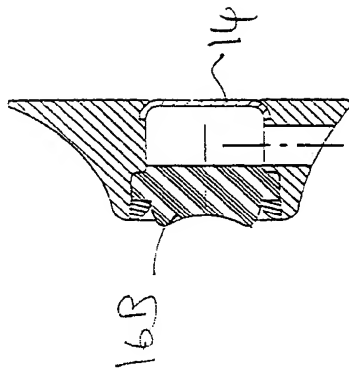


Figure 2C

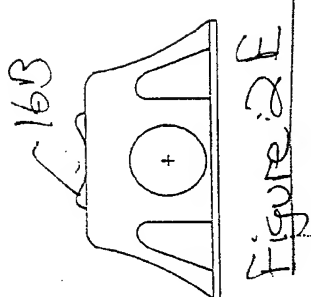


Figure 2E

Figure 3B

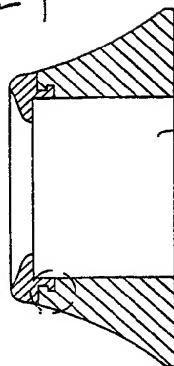


Figure 3C



Figure 3A

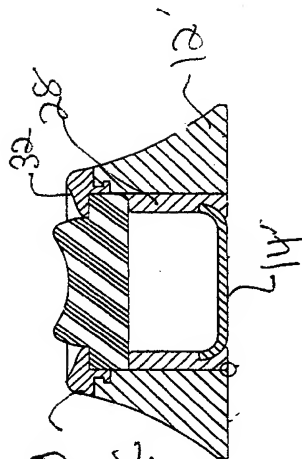
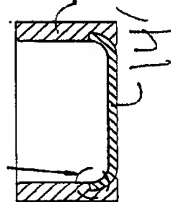


Figure 3D



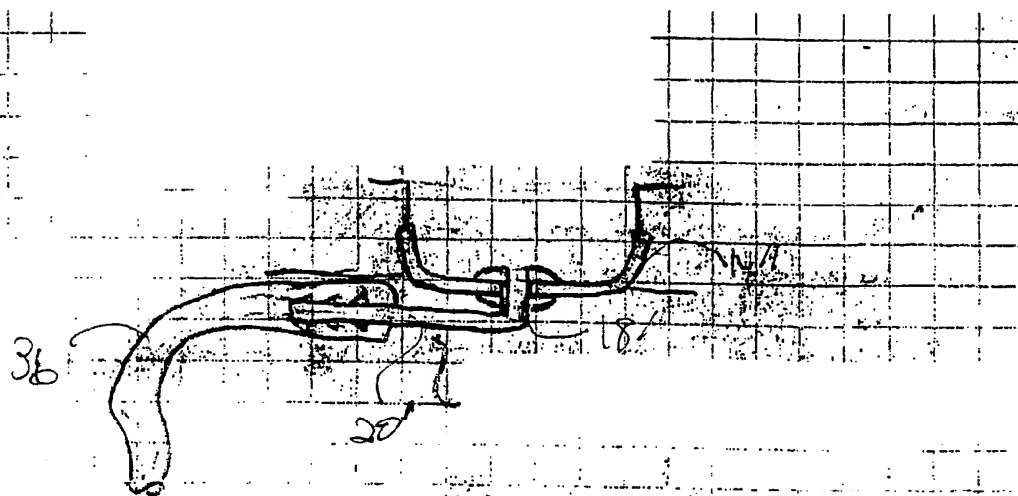


Figure 4

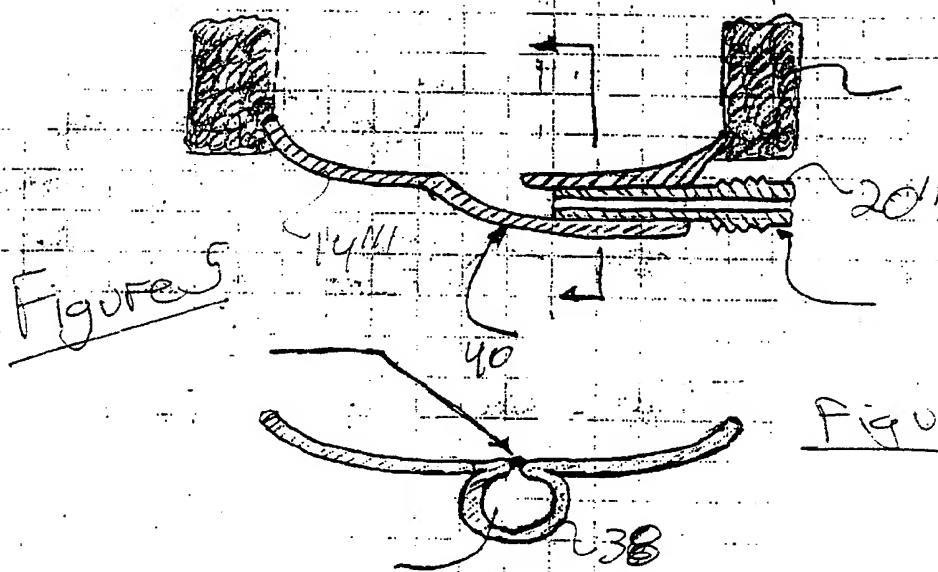


Figure 5

Figure 5A

Figure 5B

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US99/28695**A. CLASSIFICATION OF SUBJECT MATTER**

IPC(7) :A61M 11/00

US CL :604/93

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/48, 75, 93, 116, 131, 256, 890.1, 891.1, 905

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

BRS - EAST

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim N.
X — Y	US 5,360,407 A (LEONARD) 01 November 1994, Figs. 1-11, and cols. 2, and 6.	1, 2, 4, 5, 8 9, 10
X — Y	US 5,041,098A (LOITERMAN et al. ) 20 August 1991, Figs. 1-4, and cols. 4 and 5..	1-8 9, 10
X — Y	US 4,802,885 A (WEEKS et al.) 07 February 1989, figures, and cols. 3 and 4..	1-5, 8 9, 10

☒ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
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"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&" document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

22 FEBRUARY 2000

Date of mailing of the international search report

11 APR 2000

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## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US99/28695

## C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim
Y	<sup>4</sup> US 4,45,896 A (GIANTURCO) 01 May 1984, Fig. 1, and col. 3.	9
Y	US 5,295,658 A (ATKINSON et al.) 22 March 1994, Figs. 1-9.	10
Y	US 4,576,595 A (AAS et al.) 18 March 1986, Fig. 1.	10